REMARKS

Claims 1 – 12 were pending in this application. Claims 1 – 12 have been canceled and replaced by claims 13 – 24. Also, claims 25 and 26 have been added in this amendment. Therefore, claims 13 – 26 are now pending in this application.

The Examiner rejected Claims 1-4 and 6-12 under 35 U.S.C. §112, first paragraph, as allegedly failing to enable a person skilled in the relevant art to practice the invention commensurate in scope with those claims. The Examiner also rejected claim 1 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. The Examiner rejected claims 1- 12 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner also rejected claims 1 -12 under 35 U.S.C. §101, as allegedly constituting a claim which is not a proper process claim under §101. Moreover, the Examiner has rejected claims 1 -12 under the judicially created doctrine of double patenting, in view of claims 1 – 11 of co-pending Application No. 10/727,655, and further in view of applicant's admitted prior art of record.

This response addresses all of the Examiner's rejections. In light of the rewritten claim set and the discussion herein, Applicants respectfully request reconsideration of this application. Applicants believe that this application is now in condition for allowance.

New claims

New claims 13-23 constitute a reformulation of original claims 2–11, except that claim 9 has been rewritten as two claims, claims 21 and 22, in response to the Examiner's rejection of "claim 8," as described below. Therefore, support for new claims 12-23 is found in original claims 2–11.

Support for new claims 25 and 26, which are directed to dosing sequences for producing the combination therapy, is found in the specification at paragraph [0047].

Rejection of claim 1 under 35 U.S.C. §112, first paragraph

The Examiner rejected claim 1 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention at the time the application was filed. Claim 1 has been canceled. This action is taken solely in an effort to expedite prosecution of this application; it does not acknowledge the propriety of the rejection.

Rejections under 35 U.S.C. §112, second paragraph, and 35 U.S.C. §101

As noted above, the Examiner rejected claims 1-12 under 35 U.S.C. §112, second paragraph, as allegedly indefinite because the claims do not set forth any steps involved in the method or process. Additionally, the Examiner rejected claims 1-12 under 35 U.S.C. §101, as allegedly constituting claims which are not proper process claims under §101, because they allegedly recite a use without any positive steps delimiting how this use is actually practiced. Additionally, the Examiner asserted that the phrase "e.g." in claim 8 rendered that claim indefinite, and the Examiner further alleged that the presence in one claim of two ranges, namely a broader range and a narrower range within that broader range, is also considered indefinite.

In response, Applicants note initially that since claim 1 has been canceled, the rejection of that claim is now moot. Secondly, Applicants respectfully point out that claim 8 contains no term "e.g." and no broad and narrow ranges. Applicants assume that the Examiner has intended this rejection to apply to claim 9. Applicants have rewritten claims 2-12 in method-of-treatment format, where "...comprising administering to a patient in need thereof...a combination..." constitutes the positive step for practicing the claimed method. Since the absence of such step was also the basis for the Examiner's rejection of claims 2-11 under 35 U.S.C. §101, Applicants respectfully assert that the rejections of these claims under both 35 U.S.C. §101 and 35 U.S.C. §112, second paragraph, have been overcome.

Rejection of claim 1 under 35 U.S.C. §112, first paragraph

With regard to the rejection of claims 1-4 and 6-12 under 35 U.S.C. §112, first paragraph, as allegedly failing to enable a person skilled in the relevant art to practice the invention commensurate in scope with those claims, Applicants note that because these claims have been canceled, the rejection is now moot. However, in the expectation that some of the Examiner's reasons for rejecting claims 2-4 and 6-12 may possibly carry over into corresponding claims 13-15 and 18-24, Applicants respectfully request the Examiner's consideration of the following remarks.

The Examiner has acknowledged that the specification is enabling for the specific potassium channel opener flupirtine in combination with specific sodium channel-influencing substances. (In line 2 of page 2, the Examiner has written "sodium" in place of "potassium," but we assume this to be inadvertent.) However, the Examiner asserted that the specification is not enabling for "potassium channel openers in combination with sodium channel inhibiting or –influencing substances."

With respect to the broad genus of potassium channel openers, solely in an effort to expedite prosecution of this application, claim 1 has been canceled; new claims 13-26 are all directed to combinations comprising the potassium channel opener flupirtine or a therapeutically utilizable salt thereof. With respect to the genus "sodium channel inhibiting or –influencing substances," Applicants respectfully direct the Examiner's attention to the specification at Paragraphs [0004], [0005], and [0006], in which, with a variety of examples, the correlation is clearly made between reduction in muscle tone and sodium channel inhibition or –influence.

Noting that under MPEP §2164.04 "[t]he examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention," Applicants respectfully submit that the Examiner has failed to meet this burden in connection with the rejection of sodium channel inhibitors and –influencing substances in the original claims. Quoting the *Marzocchi* case, the MPEP states that "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure. *In re Marzocchi* 439 F.2d 220, 224, 169 U.S.P.Q. 367, 370

(C.C.P.A. 1971) Similarly, the MPEP continues, "the minimal requirement is for the examiner to give reasons for the uncertainty of the enablement." *In re Bowen*, 492 F.2d 859, 862-63, 181 U.S.P.Q. 48, 51 (C.C.P.A. 1974).

Applicants have searched the office action for the Examiner's reasons to support an allegation of lack of enablement. Applicants note that the Examiner has stated that sodium channel inhibitors comprise "a structurally diverse group of drug [*sic*] with their pharmacological activity vastly different from each other depending upon their different site of action." (Office Action, at page 3, lines 11-13) The Examiner goes on to allege that "[t]he specification does not provide any competent evidence or disclosed tests that all ... 'sodium channel-inhibiting or -influencing substances' that may not necessarily have similar structures would behave similarly as the demonstrated ...sodium channel inhibitor tolperisone." (Office Action, at page 3, lines 16-20). However, the Examiner has acknowledged that the specification discloses the following suitable as sodium channel inhibitors and influencing substances, tolperisone, eperisone, silperisone, riluzole, propafenone, lidocaine, flecainide, and metixean. Thus, the specification provides eight examples of structurally diverse sodium channel inhibitors.

In response to the Examiner's contention that that "[t]he specification does not provide any competent evidence or disclosed tests that all ... 'sodium channel-inhibiting or -influencing substances' that may not necessarily have similar structures would behave similarly," Applicants respectfully submit that under MPEP §2164.04 they are not required to do so. Rather, under the cases cited, Applicants respectfully submit that it is incumbent on the Examiner to explain why the discussion provided by the specification, at Paragraphs [0004], [0005], and [0006], which correlates the muscle-tone reducing properties of eight structurally materials with their sodium channel inhibiting and –influencing properties is insufficient, particularly in light of the fact that sodium channel inhibitors and –influencing substances constitute a class of materials that is well-known and recognized in the art. (For a review article, see Obrenovitch T.P., *Int Rev Neurobiol.* 1997;40:109-35)

.Lacking such an explanation, Applicants respectfully submit that a rejection of new claims 13-26 on this basis would be improper.

Double Patenting Rejection

The Examiner has rejected claims 1-12 under the judicially-created doctrine of double patenting over claims 1-11 over commonly owned copending Application Ser. No.10/727655 ("the '655 application"), in view of Applicants' prior art of record, particularly Kornhuber *et al.*, *J. Neural. Transm.* 1999; 106:857-67, alleging that the claims of the two applications are not patentably distinct. Although the claims of the both present application and the '655 application have been amended, Applicants assume that the Examiner would impose an obviousness-type double patenting rejection on the new claims as well. Therefore, solely in an effort to expedite prosecution of this application, Applicants have provided with this response a terminal disclaimer.

In view of the amendments and discussion provided above, Applicants respectfully submit that this application is now in condition for allowance, which action is earnestly solicited.

Respectfully submitted,

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